(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of [phthalocyaninato (2-)] copper shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 34947, Aug. 2, 1983, as amended at 50 FR 16228, Apr. 25, 1985; 51 FR 22929, June 24, 1986; 51 FR 28930, Aug. 13, 1986; 51 FR 39371, Oct. 28, 1986; 52 FR 15945, May 1, 1987; 55 FR 19620, May 10, 1990; 64 FR 23186, Apr. 30, 1999]

§ 74.3102 FD&C Blue No. 2.

(a) *Identity.* The color additive FD&C Blue No. 2 shall conform in identity to the requirements of § 74.102(a)(1).

(b) *Specifications.* (1) The color additive FD&C Blue No. 2 for use in coloring surgical sutures shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

Isomeric colors, not more than 18 percent.

Lower sulfonated subsidiary colors, not more than 5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 85 percent.

(2) The color additive FD&C Blue No. 2–Aluminum Lake on alumina for use in bone cement shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions.* (1) The color additive FD&C Blue No. 2 may be safely used for coloring nylon (the copolymer of adipic acid and hexamethylene diamine) surgical sutures for use in general surgery subject to the following restrictions:

(i) The quantity of color additive does not exceed 1 percent by weight of the suture;

(ii) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980); and

(iii) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissues.

(2) The color additive FD&C Blue No. 2–Aluminum Lake on alumina may be safely used for coloring bone cement at a level not to exceed 0.1 percent by weight of the bone cement.

(3) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which the color additive FD&C Blue No. 2 and the color additive FD&C Blue No. 2–Aluminum Lake on alumina are used.

(d) *Labeling.* The labels of the color additive FD&C Blue No. 2 and the color additive FD&C Blue No. 2–Aluminum Lake on alumina shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 2 and its lake shall be certified in accordance with regulations in part 80 of this chapter.

[64 FR 48290, Sept. 3, 1999]

§ 74.3106 D&C Blue No. 6.

(a) *Identity.* The color additive D&C Blue No. 6 is principally [$\Delta^{2,2'}$-biindoline]-3,3′ dione (CAS Reg. No. 482–89–3).

(b) *Specifications.* D&C Blue No. 6 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Volatile matter at 135 °C (275 °F), not more than 3 percent.

Matter insoluble in *N*,*N*-dimethylformamide, not more than 1 percent.

Isatin, not more than 0.3 percent.

Anthranilic acid, not more than 0.3 percent.

Indirubin, not more than 1 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 95 percent.

(c) *Uses and restrictions.* (1) D&C Blue No. 6 may be safely used at a level—

(i) Not to exceed 0.2 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures for general surgical use;

(ii) Not to exceed 0.25 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for general surgical use;

(iii) Not to exceed 0.5 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for ophthalmic surgical use;

(iv) Not to exceed 0.5 percent by weight of the suture material for coloring polypropylene surgical sutures for general surgical use; and

(v) Not to exceed 0.5 percent by weight of the suture material for coloring polydioxanone synthetic absorbable sutures for ophthalmic and general surgical use.

(2) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which the color additive is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Blue No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[49 FR 29956, July 25, 1984; 49 FR 34447, Aug. 31, 1984, as amended at 50 FR 30698, July 29, 1985]

§ 74.3206 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 shall conform in identity to the requirements of § 74.1206(a).

(b) *Specifications.* The color additive D&C Green No. 6 for use in medical devices shall conform to the specifications of § 74.1206(b).

(c) *Uses and restrictions.* (1) The color additive D&C Green No. 6 may be safely used at a level

(i) Not to exceed 0.03 percent by weight of the lens material for coloring contact lenses;

(ii) Not to exceed 0.75 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures, including sutures for ophthalmic use;

(iii) Not to exceed 0.1 percent by weight of the suture material for coloring polyglycolic acid surgical sutures with diameter greater than U.S.P. size 8–0, including sutures for ophthalmic use;

(iv) Not to exceed 0.5 percent by weight of the suture material for coloring polyglycolic acid surgical sutures with diameter not greater than U.S.P. size 8–0, including sutures for ophthalmic use;

(v) Not to exceed 0.21 percent by weight of the suture material for coloring poly(glycolic acid-*co*-trimethylene carbonate) sutures (also referred to as 1,4-dioxan-2,5-dione polymer with 1,3-dioxan-2-one) for general surgical use; and

(vi) Not to exceed 0.10 percent by weight of the haptic material for coloring polymethylmethacrylate support haptics of intraocular lenses.

(2) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which D&C Green No. 6 is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 13022, Mar. 29, 1983, as amended at 51 FR 9784, Mar. 21, 1986; 51 FR 37909, Oct. 27, 1986; 58 FR 21542, Apr. 22, 1993]

§ 74.3230 D&C Red No. 17.

(a) *Identity and specifications.* The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317(a)(1) and (b).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lens in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of section 510(k), 515, and 520(g) of the Federal Food, Drug, and